



FR Doc # 04-7984
PUBLIC COMMENT 8400048

July 1, 2004

Substance Abuse and
Mental Health Services Administration
5600 Fishers Lane, Rockwall II, Suite 815
Rockville, Maryland 20857

Docket #: 04-7984

Dear Sir/Madam:

The American Association for Clinical Chemistry welcomes the opportunity to comment on the Substance Abuse and Mental Health Services Administration's (SAMHSA's) April 13, 2004 proposed revisions to the mandatory drug testing guidelines. AACC largely agrees with the changes proposed by the agency, as well as the limitations imposed on the alternative methods for conducting drug testing. Our specific comments follow:

2.2 Under what circumstances can the different types of specimens be collected?

AACC supports the expansion of the kinds of specimens that can be tested for drugs-of-abuse, such as hair, oral fluid and sweat, as long as the limitations specified by the agency are adopted. As SAMHSA acknowledges there are a number of scientific issues associated with each of the new methods of testing, particularly oral fluid and sweat, which need to be addressed before they can be used in many instances. Therefore, we believe the agency's cautious approach is warranted and the best course of action.

3.7 What are the cutoff concentrations for urine specimens?

AACC also supports SAMHSA's lower cutoff levels. The April 13th notice would reduce the initial cutoff concentration for cocaine metabolites from 300ng/mL to 150 ng/mL along with a corresponding decrease in the confirmatory test cutoff concentration from 150 ng/mL to 100 ng/mL. Similarly, the agency has lowered the initial cutoff concentration for amphetamines from 1000 ng/mL to 500 ng/mL and the confirmatory test cutoff concentration from 500 ng/mL to 250 ng/mL. We believe these changes are appropriate.

SAMHSA cutoff levels and clinical laboratory testing

Earlier this year, the Food and Drug Administration (FDA) solicited public input on the type of data that manufacturers provide regarding drugs of abuse submissions.

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Throughout the document, the agency repeatedly referenced the SAMHSA cut-off levels as if those standards applied to all settings. As you know, they do not. In fact, most drugs of abuse testing occur in emergency rooms, rehabilitation programs and other clinical settings to diagnose and/or treat patients. In those instances cutoff levels are irrelevant. Although this issue is not within your purview, we urge you to contact the FDA and request that drugs of abuse labeling specify for users that "SAMHSA cutoff concentrations many not be appropriate for clinical toxicology testing." Hopefully, this will eliminate any confusion on the part of the end user, so that they don't inappropriately use a test kit intended for workplace testing in a clinical setting.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (507) 284-3480, or Vince Stine, Director, Government Affairs, at (202) 835-8721.

Sincerely,

A handwritten signature in black ink that reads "Thomas P. Moyer". The signature is written in a cursive style with a large, sweeping initial "T".

Thomas Moyer, PhD
President, AACC